Finn, Thomas

From: Smith, Liz [lsmith@Dendreon.com]
Sent: Friday, January 15, 2010 12:40 AM
To: Finn, Thomas
Subject: Response to request for information (January 14)
Attachments: FDA Request_Product_20100114.pdf

Hi Tom,

Attached is our response to your request for information regarding the process and the non-infusion rates. It took us a bit to combine datasets to calculate non-infusions and the reasons for non-infusion, so I am sorry we are just getting this to you. Please let us know if you have any questions.

Warm Regards,

Liz

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From: Finn, Thomas [mailto:Thomas.Finn@fda.hhs.gov]
Sent: Wednesday, January 06, 2010 7:18 AM
To: Smith, Liz
Subject: RE: A few more CMC questions

Thanks Liz. Hope you had a nice holiday.

Tom

From: Smith, Liz [mailto:lsmith@Dendreon.com]
Sent: Wednesday, January 06, 2010 10:17 AM
To: Finn, Thomas
Cc: Tull, Lori
Subject: Re: A few more CMC questions

Hi Tom,

We will get back to you on these shortly.

Warm regards,

Liz

From: Finn, Thomas <Thomas.Finn@fda.hhs.gov>
To: Smith, Liz
Cc: Tull, Lori <Lori.Tull@fda.hhs.gov>
Sent: Wed Jan 06 06:45:28 2010
Subject: A few more CMC questions

Hi Liz,

I know you're busy over there but I have a few, hopefully quick questions:

- I noted in some of your lot line listing that the percent b(4) in the APH ranged from as little as b(4) b(4). Some times this seems to be attributable to the patient because similar numbers are obtained from the same patient for 2 or 3 of the APH, whereas in other cases it varies a lot from the same patient. When the percentage is very low do you still follow through with the SOP and perform the b(4) b(4)? I assume the answer is yes, but just wanted to check. With regards to the upper end of the spectrum, when the percent b(4) is high can that be attributed to a leukapheresis problem or differences in the efficiency of apheresis equipment? Have you noted any differences in the APH quality from different apheresis sites over the years?
- In amendment 33, table 8 "Summary of leukapheresis and Product Infusions, Intent-to-Treat Population you have indicated that for sipuleucel-T treated patients about 1/3 of subjects required a 3rd leukapheresis. Was that typically due to complications with the apheresis that required another visit, or were there situations where insufficient APH volume was collected or an in-process or final product release criterion was not met?
- In amendment 33 you have listing 16.2.6.13 (begins on page 4890 of 5667) that provides a line listing on cell product parameters. It appears that roughly 10% of the time a product lot was not infused. I assume most of these were due to medical reasons. Were any of these due to a product not meeting in-process or final product release testing? Were any of them not infused because the shelf life (dating period) had expired?

I don not need answers to these questions immediately (I have plenty to keep me busy), but would appreciate some feedback from your end.

Thanks,
Tom

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